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BACCIS-II, is a randomized controlled trial of an outreach intervention model designed to increase the rate of periodic mammography and clinical breast exam among underserved women. The purpose is to assess the feasibility and cost-effectiveness of BACCIS-II, a moderate level of intervention, compared retrospectively with the more intensive predecessor, BACCIS, and compared with a minimal (control group) intervention. In BACCIS, paid full-time outreach workers provided motivation, education and support to women over time, resulting in increased routine, periodic screening. However the model was very costly. In BACCIS-II, women in low-income communities are encouraged to become "links" to the community, volunteers who receive a modest incentive ($5 per eligible woman) to identify friends and family members at risk for late stage diagnosis (age 45+ and no mammogram past two years), and to provide their names to project staff. Women are then called by part-time staff who offer education, motivation and assistance in obtaining screening. Currently baseline recruitment is complete, having yielded a sample of 353 women. Ninety-one have completed outreach follow-up and the final telephone survey. For all others, outreach follow-up and final surveys are ongoing.

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FOREWORD

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I. INTRODUCTION

A. *Subject, Purpose and Scope of this Research*

The study "Breast Cancer Outreach for Underserved Women: A Randomized Trial and Cost-Effectiveness Analysis," *BACCIS-II,* [1] addresses two major gaps in the current state of knowledge for breast cancer outreach to underserved women: 1) absence of affordable, cost-effective interventions, and 2) interventions specifically intended to improve lifelong, periodic early detection practices, as distinct from only initial or one-time screening. In BACCIS-II, a moderate level outreach intervention (which retains the key strengths of more intensive original BACCIS, including woman to woman contact by trusted others from within the community and contact that is sustained over time to support and reinforce repeat screening) is tested for feasibility and cost-effectiveness in comparisons with a more intensive outreach intervention (the original BACCIS) and a minimal intervention (control group). The original research plan called for recruitment and randomization of 3200 women over a three year period. Due to much slower than anticipated recruitment (a function of the less intensive outreach model), the sample size was reduced to 1000 and then to 500 (revised Statements of Work were approved).

Because of slow recruitment, the trial was temporarily halted in October 1998 in order to modify the intervention model and to conduct a pilot test of the modified model. The trial resumed in December 1998 with improved recruitment, although still not on course for attainment of sample size objectives. Ultimately, recruitment concluded in October 1999 having only recruited a total sample of 353 women. The many impediments to recruitment were detailed in the last annual report (covering the 3rd project year, July 1, 1998 - June 30, 1999).

II. BODY OF REPORT

A. *Technical Objectives: To test the feasibility and effectiveness of a moderate intensity outreach intervention*

In the last annual report, we summarized the difficulties that lead to a suspension of the trial in mid-October 1998; modifications made to the outreach protocol as a result; and resumption of the trial December 8, 1998. Unfortunately, the significant modifications made to the protocol did not result in an adequate improvement in recruitment, although we continued renewed attempts to increase recruitment throughout most of 1999. Prior to the cessation of the trial, average recruitment was 20 women per month. This only picked up to 24 women per month in the six months following resumption of the trial, dropping off precipitously to approximately 6 women per month in the last six months of recruitment. This is despite the fact that recruitment of volunteers (who in turn recruited study participants) far exceeded our original goals. A total of 214 volunteers were recruited (115 in the intervention group and 99 control). The original goal was to recruit 160. However, only 59 volunteers

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[1]The acronym "BACCIS-II" is derived from the predecessor to this research, the "Breast and Cervical Cancer Intervention Study", BACCIS, funded by the National Cancer Institute, 1991-1997. In the community, we have adapted our title and call the program the *Breast Cancer Community Information and Screening* project. In the research arena, we refer to it as BACCIS-II.

were active, meaning they recruited at least one eligible study participant. In the intervention group, active volunteers recruited an average of 6.3 women and active control volunteers recruited an average of 5.3 women. This compares with the original goal of 20 women per volunteer.

The fundamental reasons for these deficits appear to be that:

i.) women ages 45+ with no mammogram in the past two years were more difficult to identify than our data indicated at the outset of the trial;
ii) lay persons need substantial training and motivation to do the outreach needed in a project such as this;
iii.) volunteers were most effective when our paid staff worked very closely with them. However, this no longer qualified as "moderate intensity."

Currently, baseline recruitment is complete and outreach follow-up and final surveys are in progress. Because of our efforts to reach the goal of 500 women, we extended the period of recruitment until October 1999, the very latest we could recruit women and still complete follow-up and final survey work within a no-cost-extension year. The grant period ended May 30, 2000 and we are now in that no-cost-extension period. Follow-up counseling of study participants by staff is ongoing for those recruited less than 14 months ago; and final telephone surveys are being conducted with women whose 14-month follow-up period has concluded. We will conclude all follow-up by January 2001 and all analyses and reporting by May 2001.

Baseline characteristics are shown in Table 1. To date 91 final surveys have been completed. In the intervention group, 82% of women have had a mammogram since baseline compared with 65% of women in the control (p=.098). This trend is in the desired direction although the small sample thus far precludes demonstration of a significant difference. We expect, upon completion of the final surveys, to demonstrate a significantly higher rate of screening in the intervention group, indicating effectiveness of the intervention, if not cost-effectiveness. Thus far, 19 women in the intervention group have had *two* mammograms since baseline. This demonstration of repeat mammography is the ultimate goal of the study and the basis for the "woman to woman" approach. We have more repeat mammography information on women in the intervention group since this is reported as part of outreach follow-up. Thus, we do not yet know the comparable rate among controls.

See Appendix: Challenges in Breast Cancer Outreach to the Underserved. Pasick RJ, Stewart SL, Phillips K, and Davis P. Presentation to the Era of Hope DOD Breast Cancer Research Program. June 9, 2000. Atlanta, Georgia.

Table 1. Baseline Characteristics

(n=353)

	Intervention (n=231)	Control (n=122)
Mean Age	57.1	59.9
Race	**%**	**%**
African American	17	47
Latina	68	21
White	11	25
Other	4	7
No Health Insurance	64	27
Never heard of mammogram	8	3
Years since last mammogram		
0-2	0	0
>2-5	49	51
>5	9	14
don't know	3	6
never	39	29

B. *Technical Objectives: Evaluate cost-effectiveness of three levels of intervention*

We have completed a draft manuscript on the CEA for BACCIS-I, however this process has revealed some gaps in the data that are undergoing further analysis. This paper will be completed and submitted by the conclusion of the no-cost-extension year.

In this year we will also complete a manuscript that discusses the issues involved in evaluating the costs and effectiveness of community-based interventions such as BACCIS-I and BACCIS-II. We have learned a great deal about the challenges involved in evaluating interventions and approaches to overcome them, so that these "lessons learned" can be applied to future interventions.

Lastly, we will prepare a final report that summarizes the analyses discussed above.

III. Summary of Accomplishments Associated with Each Task from Approved Statement of Work

Technical Objectives: To test the feasibility and effectiveness of a moderate intensity outreach intervention

Task (as Originally Proposed)	**Status**
1. Adapt/pre-test BACCIS model	complete
2. Develop/pre-test baseline survey	complete
3. Recruit 20 businesses/agencies/ organizations (intervention arm numbers only)	reduced to 15/ complete
4. Train 80 Women's Health Leaders by month 9	complete (recruited and trained 115 Women's Health Leaders in the intervention group and 99 trainees in control group)
5. Enroll & follow-up 1600 women in each of intervention & control by month 40	Enrolled 353; follow-up completed for 91 women and ongoing for 262 Follow-up will end January 2001
6. Complete final survey of 3200 women by month 43	final survey completed for 91 women final surveys will be completed by March 2001
7. Complete process evaluation analyses by month 43	in progress
8. Analyses and reporting on baseline to follow-up changes by month 48	in progress

Technical Objectives: Evaluate cost-effectiveness of three levels of intervention

Task (as Originally Proposed)	**Status**
9. Research relevant literature	complete
10. Develop cost-effectiveness analysis design	complete
11. Develop data collection approaches and instruments	complete
12. Monitor collection of intervention cost data and effectiveness data	complete
13. Develop analytic model and input data	in progress
14. Complete societal and organizational analyses and reporting	in progress

III. Key Research Accomplishments and Reportable Outcomes

- Recruitment into the trial is completed, albeit with very disappointing results.

- These results are an important indication that a moderate intensity intervention to reach underserved women may not be feasible.

- Despite the fact that recruitment was low, the woman to woman approach to outreach and follow-up appears once again to effectively increase screening rates in underserved communities.

- While we do not expect to demonstrate cost-effectiveness of any of the three interventions (BACCIS-I due to very high costs, BACCIS-II moderate intensity intervention due to high costs associated with low feasibility, and BACCIS-II minimum intensity intervention due to low effectiveness), we will document the costs and effectiveness of these interventions to serve as benchmarks for other interventions. This will be an important contribution to the literature on screening outreach.

IV. Conclusions

Until the study is complete, we cannot conclude how effective the intervention has been in comparison with the control condition. However, we can draw one preliminary conclusion regarding the feasibility of the intervention: *Outreach to underserved women using lay health workers* ***is*** *time-consuming and costly. There may be no way of streamlining recruitment and education of women through this mechanism.* Furthermore, intensive and ongoing support of lay health workers is required and modest monetary incentives do not compensate for lack of such support and training. Thus, the search for cost-effective means of bringing underserved women into screening must continue.

Other preliminary conclusions address the complexity of conducting randomized clinical trials in the community:

- Personal contact through trusted others is effective in motivating and assisting underserved women to obtain initial and repeat screening.
- Continued research is needed to identify feasible alternatives to the costly use of paid outreach workers.

Appendix

Department of Defense Presentation
"Challenges in Breast Cancer Outreach to the Underserved"
Rena J. Pasick, Susan L. Stewart, Kathryn Phillips, Patricia Davis
Era of Hope Confeence
June 8 - 12, 2000
Atlanta, GA

Challenges in Breast Cancer Outreach to the Underserved

RJ Pasick, SL Stewart,
K Phillips, P Davis

Northern California Cancer Center

Challenges in Breast Cancer Outreach to the Underserved

RJ Pasick, SL Stewart,
K Phillips, P Davis

Northern California Cancer Center

Previous Study: BACCIS

- Breast & Cervical Cancer Intervention Study (NCI)
  - full-time, paid outreach workers
  - established ongoing supportive relationships
  - provided motivation & support through initial and repeat screening

Advantages & Disadvantages

- Advantages
  - effectively reached underserved women
  - many received first ever mammogram
  - many received yearly mammograms
- Disadvantages
  - labor intensive intervention program
  - high cost of staff
  - limited generalizability

BACCIS-II

Breast Cancer Outreach for
Underserved Women:
A Randomized Trial &
Cost-Effectiveness Analysis

Objectives

- Identify underserved women ages 45+ with no mammogram in the past 2 years
  - African American, Latina, non-Hispanic White
- Encourage immediate mammogram
- Provide personal follow-up to facilitate repeat mammogram one year later
- Test the feasibility & cost-effectiveness of a less intensive intervention

BACCIS-II Adaptations

- Paid staff used only to recruit "agencies" with access to adult women
- Volunteer teams recruited from agencies
  - trained to do personal outreach & follow-up
  - received monetary incentives based on
    - women recruited
    - follow-up contacts

BACCIS-II Study Design

- Randomized, controlled trial
  - Study arms:
    - moderate level intervention (BACCIS-II)
    - minimal intervention (control)
- Pre- and post-intervention surveys
  - At baseline and ~14 months later
- Conduct cost-effectiveness analysis
  - Compare minimal, moderate, and intensive (original BACCIS) interventions

Baseline Characteristics

(n=353)

	Intervention (n=231)	Control (n=122)
Mean Age	57.1	59.9
Race	%	%
African American	17	47
Latina	68	21
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Other	4	7
No Health Insurance	64	27
Never heard of mammogram	8	3
Years since last mammogram		
0-2	0	0
>2-5	49	51
>5	9	14
don't know	3	6
never	39	29

Feasibility

- Volunteer recruitment exceeded goals
  - 214 recruited (goal was 160)
    - 115 intervention/99 control
- But recruitment of participants by volunteers fell far short of goals
  - active participation: 31% interven/23% control
  - volunteers enrolled 353 participants (women age 45+, no mammogram past two years)
  - average enrollment:
    - 6.3 women per active intervention volunteer
    - 5.3 women per active control group volunteer

Recruitment Barriers

- Volunteer recruitment:
  - competition with many other public service programs in the SF Bay Area
  - unfamiliar program model
    - one-to-one recruitment
    - long-term commitment
    - paperwork, especially surveys

Recruitment Barriers

- Participant recruitment
  - decreasing number of eligible women due to state and federal cancer screening programs
  - need for more outreach training and motivation (characteristic of more intensive intervention model)

Impact

(preliminary data, N=91)

	Intervention %	Control %
Mammogram since baseline	82	65
No mammogram since baseline	18	35

p = .098

Conclusions

- Personal contact through trusted others is effective in motivating and assisting underserved women to obtain initial and repeat screening
- Continued research is needed to identify feasible alternatives to the costly use of paid outreach workers